

REMARKS

Consideration of this application in view of the above amendments and following remarks is respectfully requested. Claims 17-31, 35, 37-78, 85-144, 147 and 150 are now pending. No claims have been amended. Claims 21-31, 35-54, 67-78 and 85-140, previously withdrawn from consideration, have now been canceled.

Claims 17-20, 55-66, 141-144, 147 and 150 stand rejected under 35 USC 103(a) over US 3,123,077 (Alcamo) in view of US 5,123,911 (Granger) and in further view of US 5,931,855 (Buncke). Applicants respectfully traverse this rejection.

Applicants would like to say a few words about the claimed invention, and then focus on differences between the claimed invention and the disclosures of the cited art. As to Applicants' claimed invention, we wish to point out that we have invented barbed sutures with, *e.g.*, a specifically recited barb arrangement. As the Examiner has already noted, but which Applicants wish to emphasize, the claimed sutures comprise barbs that are (1) offset from one another such that any plane perpendicular to the body of the suture will intersect, at most, one barb or portion thereof, and (2) the barbs are arranged in a twist cut multiple spiral disposition. As to this second element, the Examiner has taken the position that this refers to a multiple spiral disposition, and the term "twist cut" refers to a manner of making the multiple spiral disposition. Applicants essentially agree with the Examiner's characterization of this second element: the term "twist cut" in the phrase "twist cut multiple spiral disposition" is present to remind the reader of Applicants' preferred method for making the multiple spiral barb disposition. For convenience, Applicants will refer to the first element as the "offset" feature, and the second element as the "multiple spiral" feature.

Applicants respectfully contend that none of the cited prior art teaches a barbed suture wherein the barbs are configured to be both offset and multiple spiral. Furthermore, none of the cited prior art suggests these two features should be present in a barbed suture. Applicants will now review the prior art in order to support their position. Thereafter, Applicants will address the Examiner's position that these are merely design elements, and therefore *prima facie* obvious.

Turning first to Alcamo, the teaching of this reference is primarily in its Figures. Alcamo illustrates several sutures that are "roughened" in some way, where the roughening may

take the form of raised projections, or depressions, or teeth, as, for example, barbs or spicules, adapted to snag or penetrate or press into the flesh and thereby prevent slippage of the suture after each stitch (see col. 1, lines 22-26 of Alcamo). However, none of the “roughened” sutures have both the offset and the multiple spiral features of Applicants’ claimed invention. Figures 1, 2 and 13 of Alcamo illustrate the concept of using a roughened suture, rather than any particular barb configuration, and so will not be discussed further. Figures 3, 4, 5, 6 10 and 11 illustrate roughened sutures wherein the right side is essentially a mirror image of the left side, and thus none of these illustrated sutures incorporate Applicants’ offset feature. Indeed, a plane passing perpendicular through the body of these sutures would appear to transect multiple barbs. Figure 7 also appears to lack the offset feature, since it appears that the tip of one suture is located in the same transverse plane as the base of the adjacent suture. In any event, in regards to Figure 7, there is no “multiple spiral” arrangement of barbs. Figure 8 shows a suture which does not have “barbs” at all, but instead has a long spiral ridge to provide the “roughening” effect. Figure 9 shows a suture having multiple barbs, which are not “symmetrical” as in the sutures of Figures 3, 4, 5, 6, 10 and 11, however it appears clear that a plane transverse to the body of the suture could readily be drawn that would pass through at least two of the barbs. Figure 12 is the only illustration of a suture that appears to have Applicants’ “offset” feature, however, one would not look at Figure 12 and immediately see any spiral pattern to the barbs, much less a multiple spiral disposition according to Applicants’ claimed invention. Figures 14 and 15 are intended to show how roughened and smooth regions can co-exist on a suture according to Alcamo: it does not appear that any particular barb configuration is being illustrated, and in any event, it does not appear that the sutures of Figures 14 and 15 embody either of the offset or multiple spiral features of Applicants’ claimed invention. Finally, turning to Figure 16, this appears to show “scoring” a suture as a means of creating a roughened surface. There are not any barbs in the suture of Figure 16.

In view of the above analysis, it is seen that the Figures of Alcamo do not disclose a suture with barbs configured to have an offset feature and a multiple spiral feature according to Applicants’ claimed invention. The relatively short text of Alcamo likewise fails to disclose either of these features, and certainly does not disclose the idea of combining the two features into a single suture design.

Granger and Buncke can be discussed much more briefly, since they provide little or no teaching of barb configuration in a barbed suture. Granger is the easiest in this regard, since it contains no discussion of barbed sutures at all, and indeed the Examiner did not rely upon Granger's teaching for any barb configuration design. While Buncke is directed to barbed sutures, the Buncke disclosure is primarily directed to surgical procedures using one-way sutures or double-armed sutures, and contains little disclosure directed to barb configuration. However, there is some disclosure of barb configuration, including Col. 4, lines 55-60, which reads:

FIG. 1A shows in cross section an example of one type of barb configuration which can be used on the sutures of the invention. The suture 10, which may be about 100 to 500 microns in diameter, has the barbs 16 formed in a helical pattern; however, the barbs can also be formed in other patterns and by various means, as explained below.

A review of Figure 1A shows that a helical pattern of barbs can be discerned on the illustrated suture. However, Applicants respectfully remind the Examiner that this is not Applicants' claimed invention: Neither Figure 1A nor any text in Buncke shows the addition of at least a second helical pattern of barbs to the suture, so as to achieve the "multiple spiral" element of Applicants' claimed sutures, and accordingly there is no disclosure in Buncke to have a multiple spiral disposition of barbs where each of the barbs is offset with respect to every other barb, again according to Applicants' claimed invention.

Other discussion of barb configuration in Buncke is, as the Examiner has already pointed out, directed to barbed sutures having "offset" barbs. The Examiner points to Figure 16 of Buncke, which, indeed, illustrates an offset configuration for two sets of barbs. However, the Examiner is reminded that neither Figure 16 nor any other Figure or discussion in Buncke shows a multiple spiral disposition of barbs. Col. 8, line 30 to Col. 9, line 10 of Buncke contains some additional disclosure directed to barb configuration, but again, there is no disclosure therein of Applicant's claimed invention.

In summary, there is no teaching or suggestion of barbed sutures having both an "offset" feature and a "multiple spiral" feature to the disposition of the barbs on the suture.

Accordingly, Applicants respectfully contend that the combination of art cited by the Examiner does not teach or suggest Applicant's claimed invention.

The Examiner has taken the position that Applicants' claimed invention is a "mere obvious design choice". Applicants respectfully disagree. Looking just at the prior art documents themselves, without Applicants' claims as a blueprint, it is hard, if not impossible, to imagine how those document would lead one of skill in the art to Applicants' claimed invention. If the skilled person began with Buncke, one has a choice between "offset" barbs according to Figure 16 and "non-offset" barbs according to Figures 14 and 15. Buncke expresses no preference or reason to select one of these two configurations over the other. But, even assuming one selected the offset configuration, where is the multiple spiral configuration to be found? This feature is nowhere to be found in the disclosure of Buncke. Looking at Alcamo, the configurations of Figs. 3, 4, 5, 6, 10 and 11 show barbs set in a "non-offset" configuration. To combine the offset idea from Buncke with any of the sutures of Figures 3, 4, 5, 6, 10 and 11 sets up a irresolvable conflict: the two ideas are inconsistent with one another. The suture of Alcamo's Figure 8 cannot, it would seem, be prepared in a offset manner. One might separate the barbs of Figures 7, 9 or 12 so as to incorporate "offset" in the barbs, however, even if that approach was taken, that still would not provide a multiple spiral arrangement. Thus, Applicants respectfully contend that the prior art documents themselves do not suggest to the skilled person a barbed suture having the barb configuration of Applicants' claimed invention.

Next, Applicants would like to address on the Examiner's comment that, "it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art", citing *In re Aller*. While Applicants cannot disagree with this general legal principle, Applicants respectfully disagree that the fact situation present in *In re Aller* is the same or even similar to the current facts. Notably, the prior art cited by the Examiner has listed a lot of possible barb configurations, but has not taught or suggested any advantage or preference for any particular configuration, nor suggested any particular goal that should be reached upon making selections for a barbed suture configuration. Thus, this prior art does not provide any motivation to find any optimum or workable ranges – indeed, it does not teach or suggest that any of the disclosed configurations are better or worse than any other configuration. Furthermore, it does not teach or suggest

desired properties to have in a barbed suture that might, or would, be influenced by the barb configuration. Thus, it cannot be said that Applicants have followed an obvious course based on the combined teachings of Alcamo, Granger and Buncke, since those references do not teach or suggest any particular course or direction at all, or any parameters that should be studied or modified in order to provide alternative and/or improved barbed sutures. They simply illustrate a bunch of possibilities.

Next, Applicants would like to direct the Examiner's attention to Applicants' specification, which discusses the advantages which were obtained with the barbed sutures of Applicants' claimed invention. The discussion of barbed sutures having a "multiple spiral disposition" begins at paragraph 0099 of the specification. A comparison was performed between unbarbed sutures and barbed sutures with the multiple spiral pattern, as stated at paragraph 0119. Advantages for this configuration are discussed at paragraphs 0132 and 0134, partly in reference to Table 6A below paragraph 0123, and include good USP knot pull, barbed sutures of "0" size having better knot pull strength than unbarbed sutures of size 2-0 or 3-0, and nearly as good knot pull strength as unbarbed sutures of size "0". Qualitatively, paragraph 0134 discloses the finding that sutures with multiple spiral disposition afford better wound hold capacity as compared to the 120 degree spaced barbed suture, where this is advantageous especially in fat tissue. It may also be noted that placing the barbs in an "offset" configuration provides relatively more uncut diameter in any particular plane transverse to the suture length, compared to a "non-offset" configuration where there are at least two barbs cut into the suture stock at some places along the suture stock. This provides for increased integrity of the suture.

Finally, Applicants would like to address the issue of the needle diameter to suture diameter range as recited in the claims. The Examiner finds that it would be obvious to have attached the barbed suture of Alcamo to an equal diameter suture needle, and goes on to provide a couple reasons. In this regard, Applicants respectfully direct the Examiner's attention to paragraph 0201 of Applicants' specification. At the time of Alcamo, indeed even at the time of Applicants' claimed invention, there was little experience with barbed sutures. Paragraph 0201 states the prevailing view of the time:

[0201] As is well known in the art, needle diameter for surgical needles used with conventional (i.e., unbarbed) sutures is considered

unimportant, and often very thick surgical needles are used with thin conventional sutures such that the ratio of surgical needle diameter to conventional suture diameter is 4:1 or even higher, such as 4.43:1.

At the time of Applicants' claimed invention, there was no teaching or suggestion of how needle size should be selected in the case of barbed sutures. Doctors could only rely upon their experience with unbarbed sutures, and with this type of suturing, the needle size really did not particularly matter. However, needle size does matter with barbed sutures, and this is not something taught in the prior art. The Examiner has, without citation to any source, taken the position that the needle-suture attachment process would be facilitated by selecting relative needle/suture diameters according to Applicants' claimed invention. In reply, Applicants respectfully cannot agree with this comment. The ends of barbed and unbarbed sutures are typically the same, and the needle is attached to at least one of those ends, and so it does not appear that the attachment process would be impacted by whether barbs are present on the interior portion of the suture. The Examiner then contends that a stronger suture/needle combination results by selecting relative needle/suture diameters as recited in Applicants' claims. In reply, Applicants' consider that the strength of the suture/needle combination is probably the same regardless of whether there are barbs present at some point distal to the location of the needle. In any event, these are not the reasons that Applicants' prefer a needle/suture diameter range according to the claims. Referring to paragraph 0203, Applicants explain that a thinner needle allows for greater engagement of barbs in tissue, and therefore provides better closure strength to the approximated tissue. The prior art is silent as to this benefit, and is also silent as to how needles should be selected for a barbed suture.

In summary, Applicants respectfully contend that the prior art directed to non-barbed sutures (Granger) does not teach or suggest what needle/suture diameters should be selected for barbed sutures. Barbed and unbarbed sutures work differently, in that they have different mechanisms for staying affixed to tissue. Furthermore, Applicants respectfully contend that the prior art directed to barbed sutures (Alcamo and Buncke) does not teach or suggest the barb configuration recited in Applicants' claims. Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

In view of the above remarks, allowance of claims 17-20, 55-66, 141-144, 147 and 150 is respectfully requested. A good faith effort has been made to place this application in condition for allowance. However, should any further issue require attention prior to allowance, the Examiner is requested to contact the undersigned at 425-233-4944 to resolve the same.

The Director is authorized to charge any additional fees due by way of this amendment, or credit any overpayment, to our Deposit Account No. 50-2574.

Respectfully submitted,

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